# Chapter 3
# Evaluating the Screening Ecological Risk Assessment

## 3.1 Introduction

The screening ERA follows general EPA guidance as presented in the Framework (EPA 1992a) and RAGS II (EPA 1989a). The screening ERA is a generalized, simplified assessment that is conducted by assuming conservative values for parameters where data are lacking. A screening ERA assessment may be performed as part of the PA/SI or RFA effort or as the initial Tier I effort during the CERCLA RI or RCRA RFI. The screening ERA consists of the following elements:

- Problem Formulation.
- Analysis.
  - Exposure Characterization
  - Ecological Effects Characterization
- Preliminary Risk Characterization and Summary.

## 3.2 Problem Formulation

Problem formulation begins with a compilation of readily available information on the environmental setting and potential contamination problem. EPA suggests use of their environmental checklist (EPA 1993a) in conjunction with a site visit by a qualified ecologist/biologist to help determine the level of effort needed to assess ecological risk at a particular site. Knowledge of the environmental setting and potential contaminant migration pathways allows for an early determination of the presence or absence of complete exposure routes and the potential for significant ecological impacts. State and Federal laws (e.g., CWA, ESA) designate certain types of receptors (endangered species) and environments (critical habitats, wetlands) that require special consideration during the risk assessment process or protection at the remediation stage. Knowledge of pertinent state and Federal laws pertaining to natural resources and sensitive environments at the site is a key element of the problem formulation step and the identification of assessment endpoints. Ecological information on potentially impacted environments and components can be derived from installation natural resource personnel, state natural heritage reports, and Federal agencies such as the USFWS.

### 3.2.1 Chemical Data Collection and Review

Appropriate data must be used for the screening level assessment to meet its objectives. Data available from PA/SI and RFA activities are usually limited in number but should be broad in scope of chemical analysis and in the number/type of abiotic media sampled.

Sampling should have been conducted in areas of suspected contamination and background areas to distinguish site contamination from background levels and to provide information on the "worst case." If sampling was not conducted in areas of suspected contamination, the screening ERA will not provide an adequately cautious assessment of potential risk. Similarly, if a broad chemical analysis was not performed, or if data are not available for all abiotic media of potential concern, the screening ERA will be limited and cannot be used to eliminate the site from further consideration,

The following are examples of minimum requirements for data applied to a PA/SI or an RFA screening level assessment:

- Chemical-specific analyses of appropriate abiotic media of potential concern (soil, sediments, surface water).
- Data of good quality according to the analytical methodology applied.

### 3.2.2 Ecological Conceptual Site Model

A preliminary ECSM may be developed during the problem formulation. The ECSM is a simplified, schematic, diagram of possible exposure pathways and the means by which contaminants are transported from the primary contaminant source(s) to ecological receptors. The exposure scenario(s) usually include consideration of sources, environmental transport, partitioning of the contaminants amongst various environmental media, potential chemical/biological transformation or speciation processes, and identification of potential routes of exposure (e.g., ingestion) for the ecological receptors. Because this is a screening effort and knowledge of site-specific ecological receptors may be lacking, the ECSM should be quite simplified, incorporating general categories (e.g., terrestrial or aquatic biota) in place of site-specific ecological receptors.

### 3.2.3 Problem Formulation Summary

A problem formulation summary typically includes the following:

- The environmental setting: contaminants expected, and maximum (or 95% upper confidence limit [VCL]) concentrations on a medium-by-medium basis.
- Contaminants and likely categories of ecological resources and receptors that could be affected.
- The complete exposure pathways that may exist within the impacted area.

Assessment and measurement endpoints are generally identified in the screening BRA. For the screening ERA, assessment endpoints include any likely adverse ecological effects on ecological resources of concern, for which exposure pathways are complete, as determined from the information listed above. Measurement endpoints are based on available toxicity values from the literature (i.e., toxicological endpoints). Through the exposure-response evaluation, exposure at or above levels at which adverse ecological effects might be expected are established from the contaminants and exposure pathways of concern.

## 3.3 Exposure and Effects Analysis

The analysis process consists of two interrelated efforts: exposure characterization and effects characterization.

### 3.3.1 Exposure Characterization

The two primary objectives of the exposure characterization are (1) identification of the important ecological receptor(s) or receptor group(s) in relation to the assessment endpoint(s), and (2) selection of appropriate exposure pathways and exposure point estimates. Because it is impossible to account for all species in the ecosystems potentially impacted, a few representative receptor groups or receptor species are typically chosen for evaluation in the screening assessment, Ecological receptors with the highest potential for exposure and/or high sensitivity to exposure should be identified. Development of a preliminary ECSM (see Section 4.2.6) in conjunction with the preliminary ecological site characterization can be used to identify these receptors. In some cases, site-specific information on receptors may be lacking, for example, due to seasonal field survey constraints. Where site-specific information on receptors present at the site is limited, generic or surrogate receptors may be used. These receptors are selected using professional judgment in a manner consistent with EPA guidance (EPA 1992a) and consideration of the following:

- Ecological relevance and the assessment endpoints.
- Regulatory significance.
- Relative species sensitivities to the contaminants.
- Mensurability and predictability.

The evaluation of potential exposure pathways is one of the primary tasks of the preliminary ecological characterization. Most ecotoxicological information is currently directed toward the quantification of exposure levels for terrestrial flora (uptake) and fauna (ingestion) and for direct contact of water by aquatic organisms. While other routes may be important (e.g., inhalation and dermal absorption by mammals), they are typically not addressed in the preliminary risk screen. The risk screen focuses on those pathways with maximum expected exposure potential based on professional judgment.

The screening assessment should specify which contaminants are of particular concern from an ecological perspective. This is generally done by comparing the screening criteria to the highest detected chemical concentrations (if enough data are available, the 95% UCL on the mean may be used).[1] The range of chemical concentrations detected, as well as the number of samples collected, should be reviewed to evaluate which approach

[1] The maximum is not necessarily the most conservative approach. For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the 95th UCL can be greater than the highest measured or modeled concentration (EPA 1992h. *Supplemental Guidance to RAGs: Calculating the Concentration Term).* In these cases, if additional data cannot practicably be obtained, the highest measured or modeled value can be used as the concentration term. Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95% UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95% UCL is close to the sample mean).

is most appropriate. Environmental criteria only exist for a few of the many chemicals that may be found at a site. In some cases, chemicals for which criteria have been established may be used as surrogates or analogues for other chemicals at the site. EPA (19888). for example, provides guidance for using structure-activity relationships (SARs) as an analogue method for estimating toxicity to aquatic organisms. Where criteria do not exist for the contaminants and receptors in question, analysis of known toxic effects and possible threshold levels may be used to develop site-specific screening criteria against which field exposure data may be compared

To appropriately use. a screening criterion, the assessor must be aware of the assumed receptors, exposure pathways, and exposure factors used to derive the exposure concentration, as well as the nature of the screening criterion. If other exposure pathways are anticipated to be significant at a given site, use of the screening criterion is limited. If the screening criterion is based on acute toxicity and chemical concentrations in site media approach (but don't exceed) the criterion, that would be interpreted as evidence that chronic impacts could or are likely to occur.

For the screening exposure estimate, the highest estimated contaminant concentrations are used to estimate exposures to ensure that potential ecological threats will not be missed. Areas of maximum potential exposure are designated for each ecosystem (terrestrial, aquatic, wetland) or habitat. In the absence of sound site-specific information, preliminary exposure estimates are usually based on conservative assumptions such as:

- Area use is 100 percent (for a particular habitat).
- Bioavailability is 100 percent.
- The most sensitive life stage is present,
- Minimum body weight and maximum ingestion rate are used.

### 3.3.2 Effects Characterization

Screening level risk assessments may be largely qualitative, using simple comparisons of abiotic media concentrations to readily available screening "effects" criteria for these media, or they may employ a more quantitative investigative approach that incorporates a threshold level or dose-response assessment. In the more quantitative approach, screening level ecotoxicity values (reference diet, dose, tissue, threshold levels) are developed for the principal receptors of. concern based on the complete exposure routes. For these complete exposure routes, the lowest exposure level (e.g., concentration in abiotic media, or in diet [ingested dose]) shown to produce no adverse effects (e.g., reduced growth, impaired reproduction, increased mortality) in the receptor of concern is identified. Where no observed adverse effects levels (NOAELs) arc not available, NOAELs may be conservatively estimated from the lowest observed adverse effects level (LOAEL) or other available toxicity values. The mode of toxicity represented by the screening criterion should match the mechanism of toxicity for the contaminant in question. For example, dioxins do not exhibit acute lethality as much as they inhibit successful reproduction. Therefore the criterion for dioxins should be a reproductive measure.

Sources for obtaining ecotoxicity benchmarks in a screening assessment are generally limited to published literature and readily available criteria and information such as:

- State and Federal AWQC.
- EPA, NOAA, and Ontario sediment criteria.
- EPA on-line databases.
- ECOTOX, includes the Aquatic Information Retrieval Database (AQUIRE).
- Hazardous Substances Data Bank (HSDB) (National Library of Medicine database].
- Registry of Toxic Effects of Chemical Substances (RTECS) (National Institute for Occupational Safety and Health NOSH] database).
- Oak Ridge National Laboratory (ORNL) benchmarks.
- USAEC toxicity profiles (military compounds).
- USACHPPM information databases (military compounds).

A list of environmental resources for obtaining ecotoxicity information and values is provided in Appendix B.

## 3.4 Preliminary Risk and Uncertainty Characterization

Risk characterization is the screening, summarizing step of the risk assessment. The risk characterization

integrates information from the preceding components of the risk assessment, performs a screening evaluation (or calculation), and synthesizes an overall conclusion about risk that is complete, informative, and useful for decision-makers (EPA 19954). The preliminary risk (screen) characterization is used to document a decision about whether or not there is negligible potential for ecological impacts, based on the available information at this stage.

EPA has two requirements for the full characterization of risk (EPA 1995a,d). First, the characterization should address qualitative and quantitative features of the assessment. Second, it should identify the important strengths and qualitative as well as quantitative uncertainties in the assessment as part of a discussion of the confidence in the assessment. Risk characterization as the final process in the ERA process provides:

- Integration of the individual characterizations from the ecological effects and exposure characterizations.
- Evaluation of the overall quality of the assessment and the degree of confidence in estimates of risk and conclusions drawn.
- Description of risks in terms of extent, severity, and probable harm.
- Communication of risk assessment results to the risk manager.

Although several approaches can be used to assess risk, for the preliminary risk screen, comparisons of available criteria and/or screening ecotoxicity values to maximum conservative exposure estimates is considered adequate by EPA, where a quantitative approach is called for. The preliminary risk screen employs a conservative approach to ensure that potential ecological threats are not overlooked. In general, if the 95% UCL or maximum chemical concentration exceeds the screening criterion, further assessment of the site is probably indicated.

Particularly critical to full characterization of risk is a clear and open discussion of the uncertainty in the overall assessment and in each of its components. The discussion of uncertainty should highlight those uncertainties which would tend to reduce the degree of confidence in the conclusions drawn and therefore lessen confidence that the site can pose no threat whatsoever. A discussion of uncertainty requires comment on such issues as the quality and quantity of available data, gaps in the database for specific chemicals, quality of the measured data, use of default assumptions, incomplete understanding of general biological phenomena, and scientific judgments or science policy positions that were employed to bridge information gaps (EPA 1995d). In the screening ERA, the extent of the exceedance of the screening criteria, and the appropriateness of the screening value itself, help clarify uncertainty and should be evaluated as part of the initial screen decision-making process.

In the risk characterization and uncertainty discussion, the risk assessor should also try to distinguish between variability and uncertainty. Variability arises from true heterogeneity in characteristics such as dose-response differences between species and individuals, or differences in contaminant levels in the environment. Uncertainty, on the other hand, represents lack of knowledge, or data gaps, about factors such as adverse effects of select contaminants on select species. As a minimum requirement, the potential effect of the following uncertainty factors should be discussed:

- Uncertainties associated with the (limited) chemical database for the site (availability of site-specific data for medium of concern).
- Use of the 95% UCL or maximum chemical concentration for representing the site.
- Use of surrogate or generic receptors and worst-case exposure scenarios.
- Use of screening criteria and the associated assumptions.

The need for additional risk clarification beyond that of the screening ERA is based on project planning and scoping discussions by the risk assessors and risk managers. The baseline ERA process described in Chapters 4 through 7 includes the same elements as the screening ERA described above, but is more focused, detailed, and quantitative in its characterization of receptors, chemicals of concern, exposure pathways, effects, and uncertainty.